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PTO/SB/05 (4/98)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	24149-10
First Inventor or Application Identifier	Eilaz Babaev
Title	ULRRASONIC METHOD AND DEVICE FOR ....
Express Mail Label No.	EL007682224US

JC682 U.S. PTO 09/669312 09/25/00

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: **Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231**

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [*Total Pages* 15] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 4]
4. Oath or Declaration [ ] executed [*Total Pages* 2]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

** NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).*

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [ ] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
13. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. [ ] Other: .....

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*
    [ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____
    Prior application information: Examiner _____ *Group / Art Unit:* _____

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* *or* [X] *Correspondence address below*

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Signature	William H. Dippert	*Date*	Sept. 25, 2000

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FEE TRANSMITTAL for FY 2000

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Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12. See 37 C.F.R. §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT ($) 690.00

Complete if Known	
Application Number	
Filing Date	Eliaz
First Named Inventor	~~Elias~~ Babaev
Examiner Name	
Group / Art Unit	
Attorney Docket No.	24149-10

METHOD OF PAYMENT (check one)

1. ☑ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number: 03-3415

Deposit Account Name: Cowan, Liebowitz & Latman

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2. ☑ **Payment Enclosed:** ☑ Check ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	690	201	345	Utility filing fee	690.00
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	345	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) ~~690.00~~ 345.00

2. EXTRA CLAIM FEES

		Extra Claims		Fee from below	Fee Paid
Total Claims	25	-20** = 5	X	9	= 45
Independent Claims	2	- 3** = 0	X		= 0
Multiple Dependent					= 0

**or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	78	202	39	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim, if not paid
109	78	209	39	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) ~~690.00~~ 390.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	380	216	190	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,360	218	680	Extension for reply within fourth month	
128	1,850	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,210	241	605	Petition to revive - unintentional	
142	1,210	242	605	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	690	246	345	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	690	249	345	For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify) _____

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	William H. Dippert	Registration No. (Attorney/Agent)	26,723	Telephone	212-790=9200
Signature	William H. Dippert			Date	Sept. 25, 2000

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PTO/SB/10 (1-99)
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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN

Docket Number (Optional) 24149-10

Applicant, Patentee, or Identifier: Eilaz Babaev
Application or Patent No.: to be assigned
Filed or Issued: to be assigned
Title: ULTRASONIC METHOD AND DEVICE FOR WOUND TREATMENT

I hereby state that I *am*
☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN Advanced Medical Applications

ADDRESS OF SMALL BUSINESS CONCERN Vista Business Center, 5200 West 73rd Street
Minneapolis, MN 55439

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

☒ the specification filed herewith with title as listed above.
☐ the application identified above.
☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:
☒ no such person, concern, or organization exists.
☐ each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Gene Berghoff

TITLE OF PERSON IF OTHER THAN OWNER President

ADDRESS OF PERSON SIGNING Vista Business Center, 5200 West 73rd Street

SIGNATURE Gene Berghoff DATE 9/25/, 2000

ULTRASONIC METHOD AND DEVICE FOR WOUND TREATMENT

FIELD OF THE INVENTION

The present invention relates to methods of using ultrasonic waves in wound treatment. More particularly, the present invention relates to a method of spraying a wound surface using ultrasonic waves for delivering drugs, killing bacteria, cleansing a surface and stimulating healthy tissue cells.

BACKGROUND OF THE INVENTION

Ultrasonic waves has been widely used in medical applications, including both diagnostics and therapy as well as many industrial applications. One diagnostic use of ultrasound waves includes using ultrasonic waves to detect underlying structures in an object or a human tissue. In this procedure, an ultrasonic transducer is placed in contact with the object or tissue via a coupling medium and high frequency (1-10 MHz)ultrasonic waves are directed into the tissue. Upon contact with various underlying structures, the waves are reflected back to a receiver adjacent the transducer. By comparison of the signals of the ultrasonic wave as sent with the reflected ultrasonic wave as received, an image of the underlying structure can be produced. This technique is particularly useful for identifying boundaries between components of tissue and can be used to detect irregular masses, tumors, and the like.

Two therapeutic medical uses of ultrasound waves include aerosol mist production and contact physiotherapy. Aerosol mist production makes use of a nebulizer or inhaler to produce an aerosol mist for creating a humid environment and delivering drugs to the lungs. Ultrasonic nebulizers operate by the passage of ultrasound waves of sufficient intensity through a liquid, the waves being directed at an air-liquid interface of the liquid at a point underneath or within the liquid. Liquid particles are ejected from the surface of the liquid into the surrounding air following the disintegration of capillary waves produced by the ultrasound. This technique can produce a very fine dense fog or mist. Aerosol mists

produced by ultrasound are preferred over aerosol mists produced by other methods because a smaller particle size of aerosol can be obtained with the ultrasonic waves. One of the major shortcoming of inhalers and nebulizers is that the aerosol mist cannot be directed to a target area without an air stream, which decreases the efficiency of ultrasound.

Ultrasonic sprayers such as those sold by Sonic and Materials Inc., Misonix Inc., Sono-Tek Inc. (see, for example, U.S. Patents Nos. 4,153,201, 4,655,393, and 5,516,043) operate by passing liquid through a central orifice of an ultrasound instrument-tip. Major disadvantages of these sprayers include non-uniform particle size, heating of liquid flow, and less efficiency of ultrasound waves because of demolished end (radiation) surface of tip.

Contact physiotherapy applies ultrasonic waves directly to tissue in an attempt to produce a physical change in the tissue. In conventional ultrasound physiotherapy, an ultrasonic wave contacts the tissue via a coupling medium. Ultrasonic waves produced by the transducer travel through the coupling medium and into the tissue. The coupling medium is typically a bath of liquid, a jelly applied to the surface to be treated, or a water-filled balloon. Conventional techniques provide ultrasonic waves having an intensity of about 0.25 w/cm^2 to 3 w/cm^2 at a frequency of about 0.8 to 3 Megahertz. The treatment is applied to a skin surface for from about 1 to 30 minutes, two or three times a week. The coupling medium can provide a cooling effect which dissipates some of the energy produced by the ultrasonic transducer.

More importantly, a coupling medium or direct contact between the tissue and ultrasonic transducer is necessary to transmit the ultrasonic waves from the to the skin surface because ambient air is a relatively poor medium the propagation of ultrasonic waves.

Several beneficial effects have been reported from contact ultrasound physiotherapy, such as, for example, the following: local improvement of the blood circulation, heating of the tissue, accelerated enzyme activity, muscle relaxation, pain reduction, and enhancement of natural healing processes. Despite these beneficial effects, current techniques of medical

physiotherapy using ultrasonic waves are limited by the necessity of providing a direct contact interface between the ultrasonic transducer and the tissue to maintain an effective transmission of the ultrasonic waves from the transducer to the tissue.

The necessity of direct contact with or without a coupling medium makes current methods undesirable. Some tissue conditions may be accessible to contact ultrasound devices but would be impractical for contact ultrasound treatment. For example, fresh or open wounds resulting from trauma, burns, surgical interventions are not suitable for direct contact ultrasound treatment because of the structural nature of the open wound and the painful condition associated with those wounds. Moreover, conventional contact ultrasound may have a destructive effect on these types of open wounds due to the close proximity of an oscillating tip of an ultrasonic transducer relative to the already damaged tissue surface.

OBJECT OF THE INVENTION

It is an object of the invention to provide an improved method and device for treating wounds.

It is also an object of this invention to provide a method and device for treating wounds using ultrasonic waves.

It is a further object of the invention to provide a method and device for delivering drugs, killing bacteria, cleansing a surface, or stimulating healthy tissue cell growth.

It is a yet further object of the invention to treat a wound by spraying the surface of the wound with aerosol mist produced by ultrasonic waves.

These and other objects of the invention will become more apparent from the discussion below.

SUMMARY OF THE INVENTION

The present invention relates to a method and device for spraying a wound surface to deliver drugs, kill bacteria, or cleanse a surface by non-contact application of an ultrasound transducer tip. The method applies ultrasonic waves to the wound without requiring direct or indirect (via a traditional coupling medium) contact between the ultrasonic wave transducer and the wound to be sprayed.

The method of the invention comprises producing a directed spray of liquid particles produced by contact of the liquid with a free end surface of an ultrasonic transducer. The ultrasonic waves cause the spray to project outwardly from the distal end surface of the ultrasonic transducer, and the particle spray is directed onto the wound. The particles of the spray provide a medium for propagation of the ultrasonic waves emanating from the distal end surface. According to the method of the present invention directed particle spray created by low frequency ultrasound waves onto a wound, delivers drug, kills bacteria on that wound, increases blood flow, and removes dirt and other contaminants from that surface mechanical cleansing).

This method of drug delivery is particularly advantageous on tissues for which local topical application of a drug is desirable but contact with the tissue is to be avoided. Furthermore, the low frequency ultrasound waves used in the method energize the drug and cause penetration of the drug below the surface of the tissue. Finally, the bacteria killing method is effective when applied to the surface whether the liquid sprayed is drug (an antiseptic or antibiotic), oil, saline, distilled water, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an ultrasonic wound treatment system for use according to the present invention;

Fig. 2 is a lateral schematic view of an ultrasonic sprayer useful according to the present invention;

Fig. 3 is a partly cross-sectional view of an ultrasonic sprayer in use according to the present invention;

Figs. 4a and 4b are each a detail of the sprayer shown in Fig. 3 for spraying liquid from a radiation surface (FIG. 4a) or from a side (radial) surface, based on the Babaev effect (FIG. 4b);

Fig. 5 represents a cross-sectional view of the distal end of the ultrasonic transducer when liquid is delivered to the side or radiation surface of the transducer tip from 360° by perimeter as a top, side, bottom, etc;

Fig. 6 is a variation of the detail of Fig. 4b which illustrates the spraying effect by changing the angle between the ultrasound instrument and horizontal line from 0° to 90°;

Figs. 7a to 7m are each a cross-sectional view of a useful ultrasound tip;

Figs. 8a to 8n are each an enlarged view of a different modification of a tip end shape of the ultrasonic sprayer used according to the present invention; and

Figs. 9a, 9b, and 9c represent cross-sectional, distal, and lateral views of the top of an ultrasonic sprayer having a slot, groove, or thread.

DETAILED DESCRIPTION OF THE INVENTION

The device of the invention that produces a spray is characterized by means for first delivering the liquid to a lateral surface of an ultrasonic transducer tip adjacent to a free end surface such that the liquid is pulled to the free end surface by a vacuum (negative pressure) created by the ultrasound waves on the free end surface of the transducer tip. This effect can be achieved while the angle between the ultrasound instrument and the horizontal is modified up to 90°. (This acoustical effect of delivering liquid from radial side of a tip to the free end was discovered by the inventor of this invention and is called the "Babaev effect".) This

effect occurs when liquid is delivered to the radial surface of a transducer tip from 360° by perimeter as a top, side, bottom, etc.

For the above purpose the device must have a so-called nozzle from steel (non-disposable) or plastic (disposable) with a different design of valve. The nozzle allows delivery of liquid to the lateral surface of the transducer tip or directly to the distal side (radiation surface) of the ultrasound transducer to act as a sprayer or atomizer.

One of the major advantages of the invention is the uniformity of the spray particles generated. Because liquid is sprayed from a solid radiation surface, there is substantial uniformity of particle size, about 90% or greater, preferably from about 90 to 96 %.

The step of producing the spray can further include operating the transducer to produce ultrasonic waves having a frequency of from about 18kHz to 10,000 MHz. Frequencies below 18 kHz, i.e., from about 1 to 18 kHz, can be used as well; however, this lower range is less desirable because this range of sound wave can be uncomfortable to the patient and operator (without ear protection or the like). Frequencies in the range of from about 30 to 100 kHz are preferred, and frequencies of about 40 kHz are most preferred.

The separation distance between the free end surface of the transducer and the surface or object to be sprayed should be a "non-contact" distance of at least 0.1 in. (2.5 mm). Preferably the separation distance is from about 0.1 in. (2.5 mm) to 20 in. (51 cm), more preferably from about 0.1 in. (2.5 mm) to 5 in. (12.7 cm). The liquid to be sprayed can be any appropriate carrier such as water (regular or distilled), saline solution, or oil to be applied to tissue, such as a vegetable, peanut, or canola oil, optionally with a soluble pharmaceutical (e.g., an antibiotic), antiseptic, conditioner, surfactant, emollient, or other active ingredient. The pharmaceutical or the like is preferably present in a concentration sufficiently low to be soluble but high enough to be effective for the intended purpose.

It is within the scope of the invention that the liquid to be sprayed could comprise a mixture of two or more immiscible liquids or a heterogeneous mixture of a solution and

small particles. It is also within the scope of the invention that the spray could comprise particles, such as powder.

The spray produced according to the invention is directed to the object, surface, or tissue to be sprayed for the time and frequency required to accomplish a particular purpose or treatment. It is believed that a minimum length of spray of at least one second will be required; however, the length or duration of the spray could be from about one second to as much as a minute or more, even 30 minutes. Numerous factors or circumstances, such as, for example, the area to be sprayed (e.g., the size of a wound), the volume rate of spray produced, the concentration of active ingredient, etc., will impact upon the duration and/or frequency of the spraying. Spraying could be required from one ore more times daily to as little as two or three times a week or month.

According to the invention ultrasonic waves are applied to a wound without establishing contact, directly or indirectly, between the ultrasonic transducer and the wound. For example, surfaces of the human body especially suited for treatment with the method of the present invention include infected and inflammatory situations in open wounds, including trauma or gun shut wounds, fire and chemical burns.

In addition, the method of the present invention is particularly suited to directing a spray into orifices or other body crevices that are difficult to access.

Wound treatment according to the invention has several advantages. First, this method topically applies medicines such as liquid antibiotics to the wound surface without the need to contact infected, inflamed or painful tissue with an instrument. And second, a significant bactericidal effect occurs when a wound surface is sprayed using the method of the present invention.

Moreover, aside from the bactericidal effect and advantages of non-contact treatment, using the method of the present invention gave a significant reduction in volume used of liquid medicine used as compared with traditional methods for wound treatment. Similarly,

this allows for precise dosage of the sprayed liquid to permit a user, such as a physician, to administer the desired volume of liquid at a desired rate and duration.

It has been found that the method of the present invention decreases healing times for inflammatory and purulent infected wounds that is from about 1.5 to 3 times faster than traditional methods. This effect results from a bactericidal, blood flow increasing and mechanical cleansing effect of the atomized spray particles, which have ultrasound energy due to the ultrasonic waves. The spray mechanically scrubs the surface of tissue to remove dirt, dead tissue, and purulent buildup on the tissue surface. The mentioned healing effect also results of energized and highly activated antibiotics, drug penetration into the tissue surface up to 0.5 mm in depth under influence of ultrasound waves.

Additionally, a combination of the low frequency ultrasonic waves and the sonicated medicines (highly activated by ultrasonic energy) destroy the surface bacteria to result in a higher disinfecting property of sonicated liquids as compared to ordinarily applied liquids. The spray of the present method also stimulates healthy cell growth to aid in granulization and epithelization of the healing tissue.

Other applications of the invention can be directed to non-medical uses such as cleansing, sterilizing and coating surfaces of objects and food.

The method of the present invention offers an approach that may re-establish use of some traditional antibiotics and establish a method fighting bacteria without antibiotics when necessary. The effect of the method of the present invention in highly activating antibiotics may allow some traditional antibiotics to overcome bacteria which have become resistant to that antibiotic. Moreover, independent of the sonication effect of the antibiotics, the low frequency ultrasonic waves applied in the method of the present invention physically destroy bacteria. The combination of the highly activated antibiotics and of the low frequency ultrasonic waves in the method of the present invention produce a strong bactericidal effect

not found in mere topically application or orally ingested antibiotics. This combined effect has been shown to significantly increase the healing of purulent infected wounds.

The present method also provides a system of non-contact drug delivery without use of a compression sprayer system. This simplifies the design of a non-contact drug delivery sprayer and reduces the weight of the sprayer. More importantly, not using compression to propel the atomized particles preserves the ultrasound energy carried by the spray particles.

This ultrasound energy has been proven to destroy bacteria by action of the ultrasonic waves and by highly activated liquid medicines applied to the tissue.

The method of the present invection provides a method of compressionless non-contact drug delivery.

The invention can perhaps be better appreciated by making reference to the drawings. In Fig. 1, an ultrasonic treatment system 2 comprises an ultrasound wave generator 4, connected to an ultrasound transducer 6 by a cable 8. The wave generator 4, which is conventional, may have a front panel 10 with a power button 12, a timer 14, a control button 16, one or more displays 18, and one or more jacks 20, for example, for a footswitch (not shown). A nozzle 22 having a liquid reservoir 24 with a valve 26 is attached to the distal portion of transducer 6. Arrows 28 represent the direction of spray produced.

Fig. 2 is a simplified representation of an ultrasonic device and spray according to the invention. Transducer 6 has a distal transducer tip or horn 30. Liquid from a liquid reservoir 32 flows through a valve 34 to a position adjacent the distal radiation surface 36 of a horn 30. Transducer 6 is attached to an ultrasound source via cable 8. A liquid mist is directed in the direction of arrows 38 to target tissue or surface 40.

Fig. 3 is an enlarged, partly cross-sectional view of a section of Fig. 1 illustrating a spray created by the device according to the method of the present invention. This device is a modification and implementation of a device disclosed in U.S. Patent No. 5,076,266, which is incorporated herein by reference. As can be seen in more detail in Fig. 3, nozzle 22

surrounds ultrasound horn 30. Also, liquid reservoir 32 has a valve 34 positioned between reservoir 32 and the distal surface 36 of ultrasonic horn 30. A conical spray pattern of liquid droplets 42 is directed at a surface or tissue 44 of a target. This configuration is effective to spray liquid onto a surface and to deliver ultrasonic waves to that surface, such as, for example, the surface of a wound.

Valve 34 allows liquid to flow to distal tip 36 as drops or continuous flow through gap 46. Valve 34 may be located anywhere, including between reservoir 32 and horn 30. Mechanical movement of the horn 30 in the direction x-x causes liquid to flow to the distal end or radial surface 36.

Fig. 4(a) is a view of the ultrasonic sprayer as used in a method of the present invention for spraying liquid 48 directed to distal end (radiation surface) 36.

Fig. 4(b) is a view of the basic spraying method from side (radial) surface of the tip based on the Babaev effect. In this case liquid or drug directed to the radial surface 36 of ultrasound horn 30 becomes sonicated (ultrasonically energized), after being pulled forward by negative pressure (vacuum) created by ultrasound waves and sprays.

As shown in Fig. 5, liquid is delivered to the side or radiation surface 36 of transducer horn 30 from 360° along its perimeter as a top, side, bottom, etc.

In the embodiment of the invention shown in Fig. 6, a partial section of transducer horn 30 is elevated from the horizontal up to 90°. Due to the Babaev effect, liquid 48 still travels to radiation surface 36.

The ultrasound tip or horn can can have a regular or irregular lateral cross-section, including circular, oval, elliptical, rectangular, trapezoidal, or a combination thereof. See, for example, Figs. 7(a) to 7(g), which are each a view of a cross-section of a ultrasound tip or horn. Also, the distal end shape of the ultrasound tip or horn longitudinal cross-section may vary and may be rectangular, elliptical, oval, spherical, conical, curved, stepped, with chamfer, etc. See, for example, Figs. 8(a) to 8(n), which are each an enlarged view in section

of a different modification of a tip of the sprayer as used in the method of the present invention. The preferred shape is rectangular, because of radiation bims from ultrasound tip surface fully directed to the target(wound). With the spheric, elliptic and oval (Fig. 8(e)) form of shape end radiation beams are focused at focal point. With other form of shape end, radiation beams are getting spreaded reaching target partly.

Radial side surface of distal end of the tip may have slot (groove)or thread for liquid to be directed to the radiation surface (Fig. 9).

Figs. 9a to 9c are each a view of radial side surface of distal end of the tip which has a slot (groove)19 or thread 20 for liquid to be directed to the radiation surface.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A method of wound treatment comprising:

(a) providing a transducer having a distal radiation surface arranged a distance from the surface of a wound to be treated,

(b) causing droplets of liquid or powder to travel to an area adjacent said distal surface to provide a spray comprising waves from the transducer, and

(c) directing said spray to the wound surface.

2. The method of Claim 1, wherein the transducer is an ultrasound transducer.

3. The method of Claim 2, wherein the transducer operates at a frequency of from about 18 kHz to 10^3MHz.

4. The method of Claim 1, wherein the distal surface is positioned at least 0.1 in. from the wound surface.

5. The method of Claim 4, wherein the distal surface is positioned from about 0.1 to 20 in. from the wound surface.

6. The method of Claim 5, wherein the distal surface is from about 0.1 to 5 in. from the would surface.

7. The method of Claim 1, wherein the liquid contacts the distal surface to produce a spray from liquid flow or drops.

8. The method of Claim 1, wherein the liquid contacts a radial surface adjacent to the distal radiation surface to produce a spray from liquid flow or drops.

9. The method of Claim 1, wherein the powder contacts the distal surface to produce a spray from the powder.

10. The method of Claim 1, wherein in step (b) liquid is supplied at a different position which causes the liquid particles to be energized.

11. The method of Claim 1, wherein ultrasound waves are directed and transported to the wound through liquid or powder spray.

12. The method of Claim 1, wherein spray directed to the wound surface has irrigation and/or mechanical cleansing effect.

13. The method of Claim 1, wherein the liquid comprises one or more components selected from the group consisting of antibiotics, antiseptics, saline solutions, oils, and water.

14. The method of Claim 1, wherein the transducer distal surface is driven with constant frequency to create liquid spray.

15. The method of Claim 1, wherein the transducer distal surface is driven with a modulated frequency to create spray.

16. The method of Claim 15, wherein the transducer surface is driven with a sinusoidal ultrasound wave.

17. The method of Claim 16, wherein the wave form is rectangular.

18. The method of Claim 16, wherein the wave form is trapezoidal.

19. The method of Claim 16, wherein the wave form is triangular.

20. The method of Claim 1, wherein the transducer is driven with a pulsed frequency to create spray.

21. A transducer for generating a liquid or powder spray, said transducer having a distal radiation end having a surface, wherein the distal radiation end is irregular.

22. The transducer of Claim 21, wherein the surface has a slot or groove.

23. The transducer of Claim 21, wherein the surface has a thread.

24. The transducer of Claim 21, wherein the lateral cross-section of the distal end is circular, oval, elliptical, rectangular or trapezoidal or a combination of two or more thereof.

25. The transducer of Claim 21, wherein the longitudinal cross-section is rectangular, elliptical, oval, spherical, conical, curved, stepped, or with chamfer or a combination of two or more thereof.

ABSTRACT OF THE DISCLOSURE

The method and device of the present invention for wound treatment includes a transducer to produce waves, preferably ultrasonic waves. The transducer has tip with the distal end (radiation surface). A liquid is directed to the radiation surface wherein an directed atomized particle spray of the liquid is created upon contact of the liquid with the radiation surface. The spray directed to the wound from at least 0.1 inches transmits wave trough particles and has an irrigation, mechanical cleansing, liquid energizing and bactericide effect.

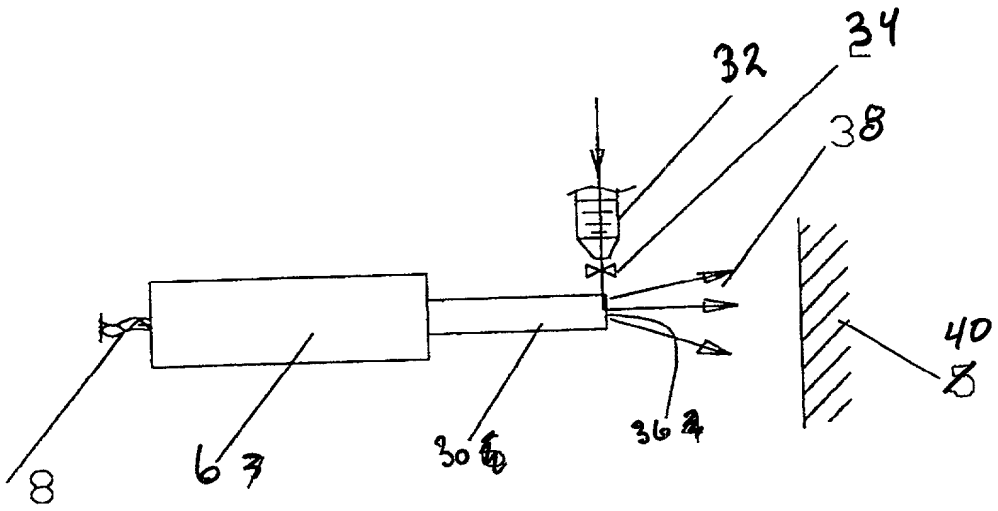

FIG. 2

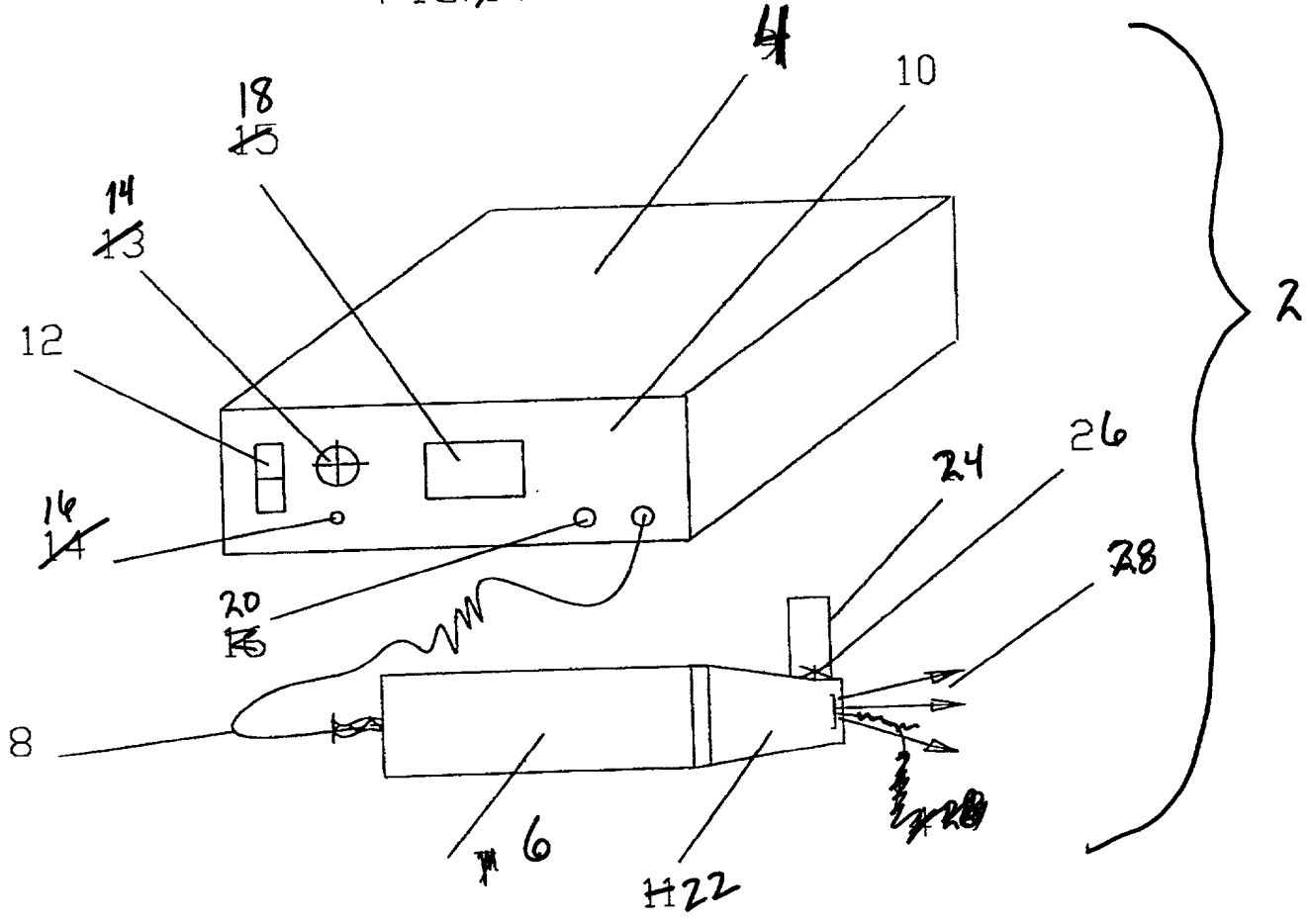

FIG. 1

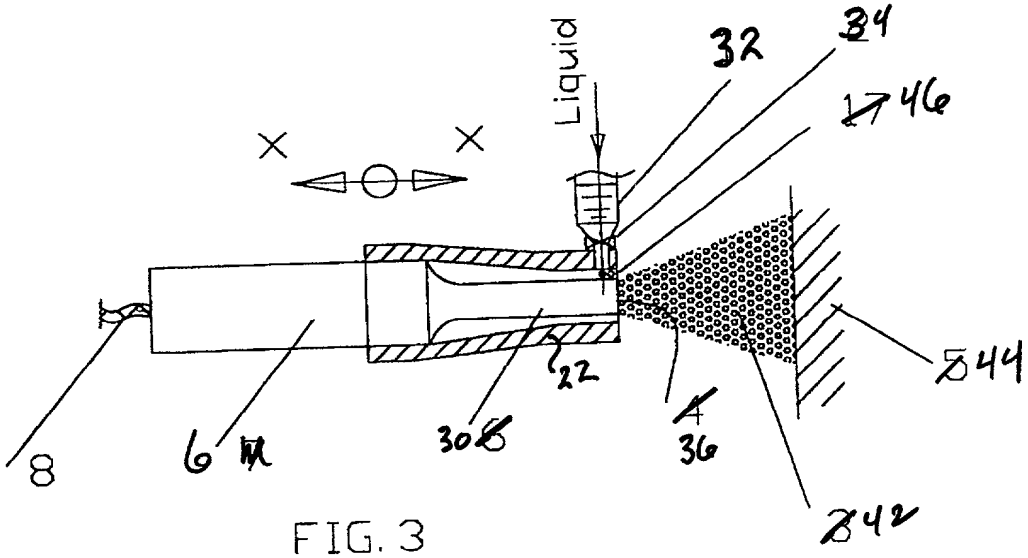

FIG. 3

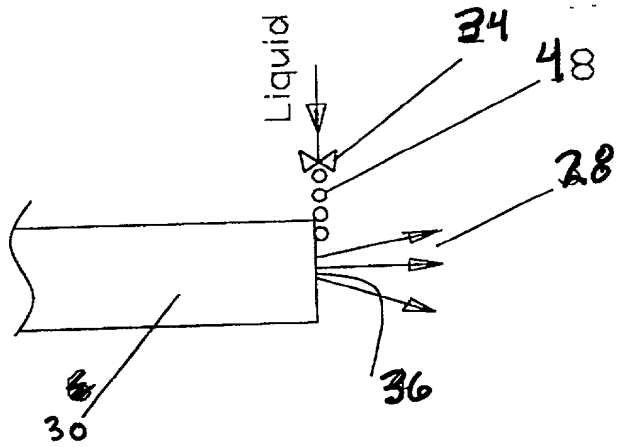

FIG. 4a

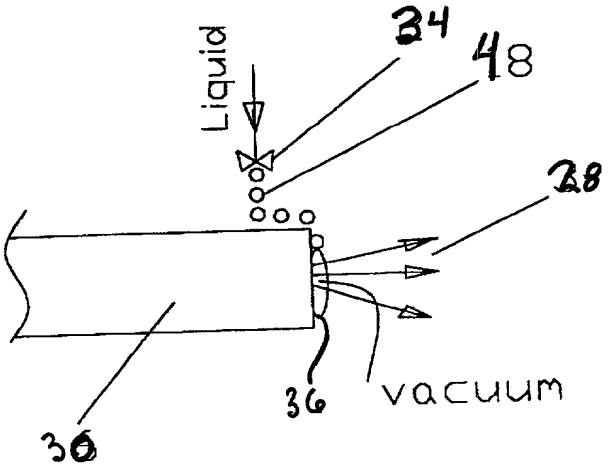

FIG. 4b

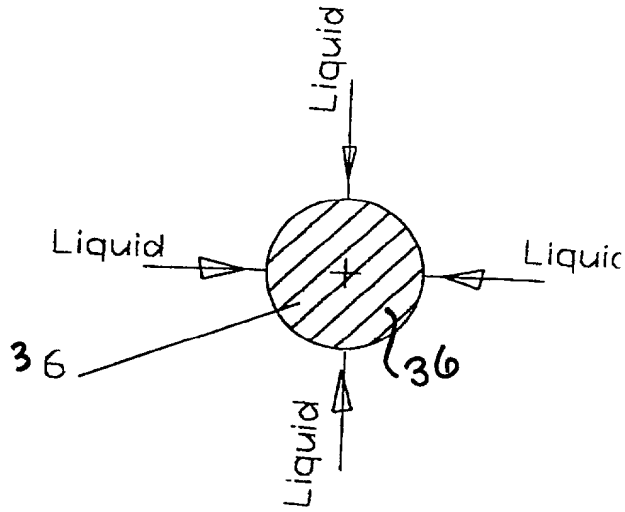

FIG. 5

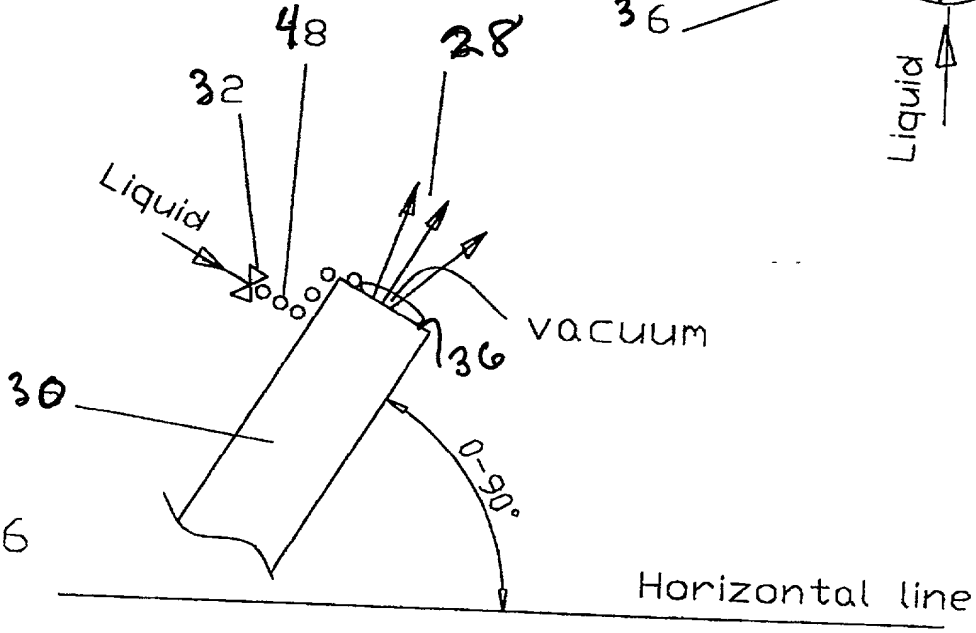

FIG. 6

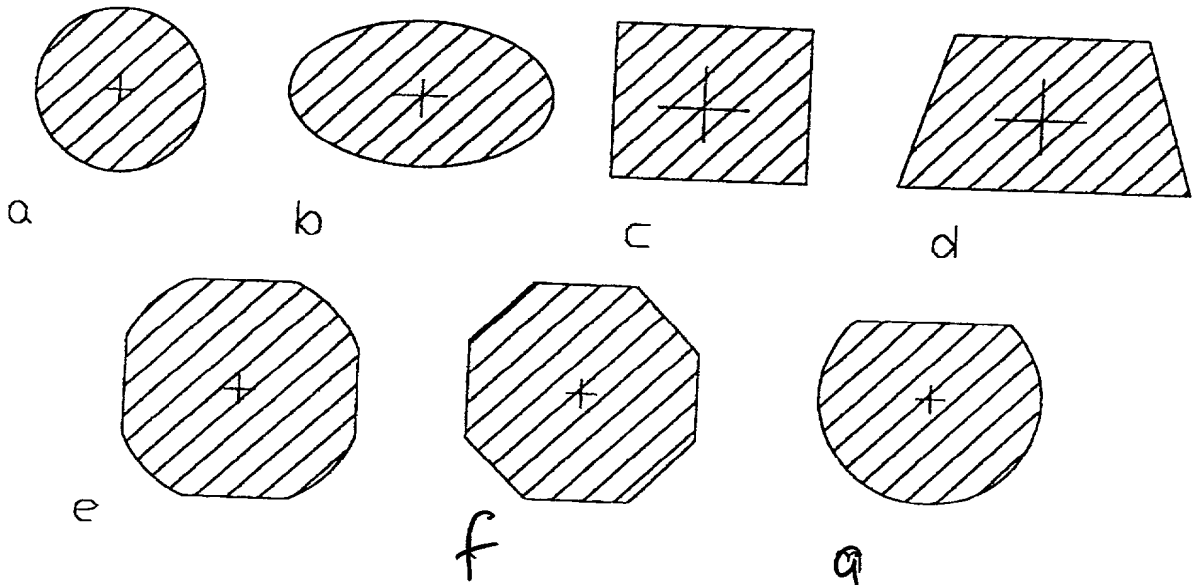

FIG. 7

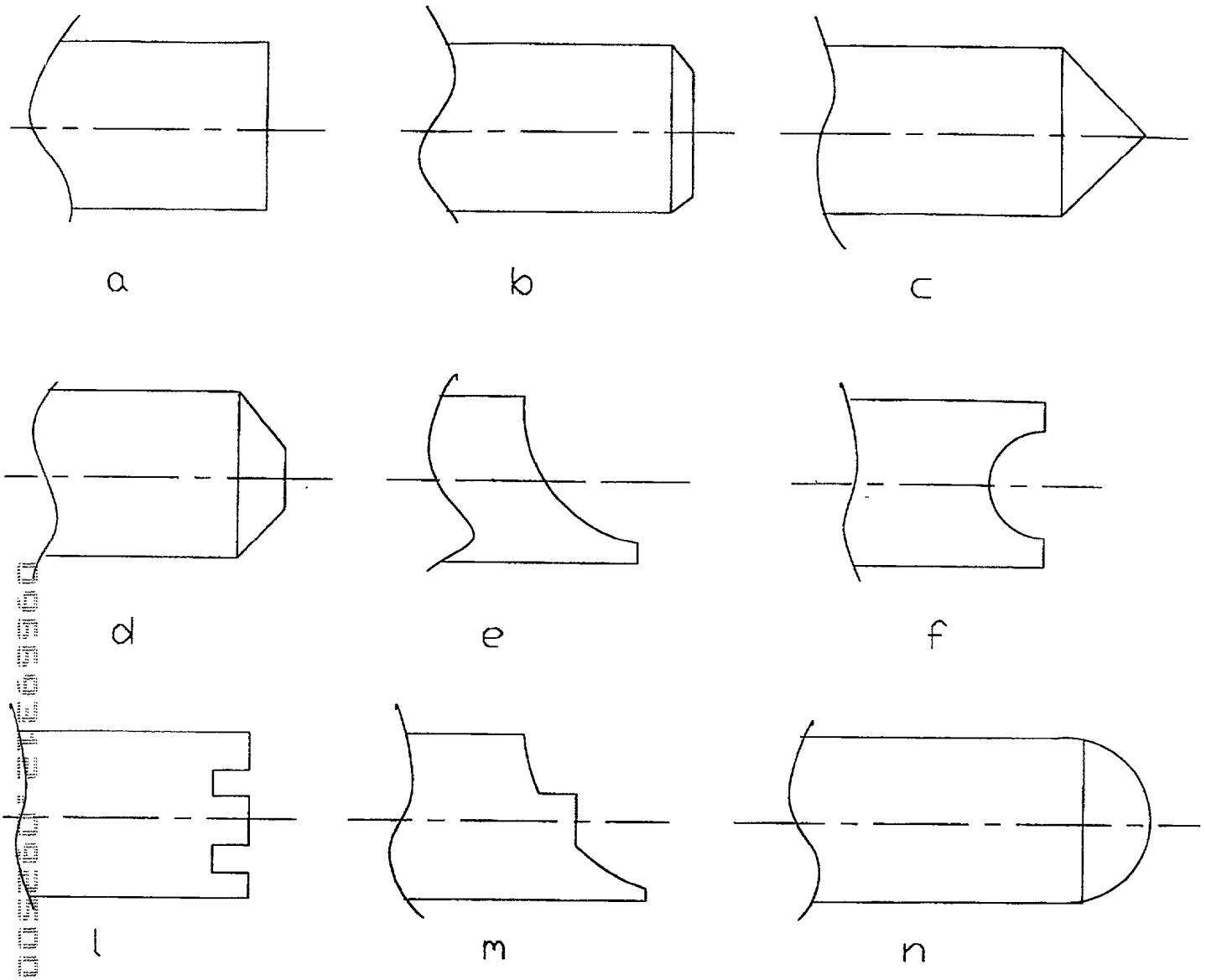

FIG. 8

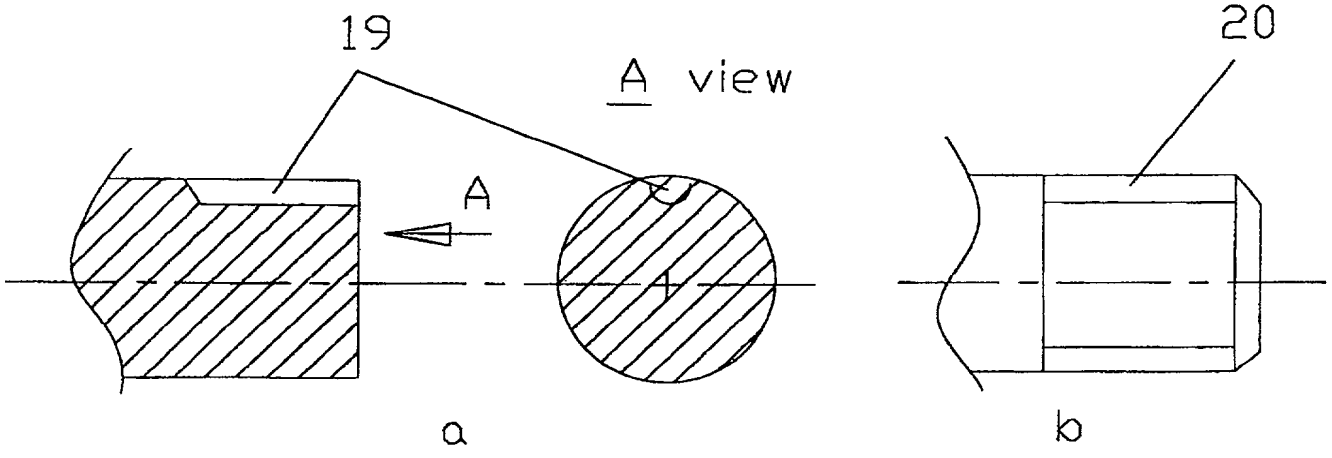

FIG. 9

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	24149-10
First Named Inventor	Eilaz Babaev
COMPLETE IF KNOWN	
Application Number	/ to be assigned
Filing Date	to be assigned
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ULTRASONIC METHOD AND DEVICE FOR WOUND TREATMENT

(Title of the Invention)

the specification of which
☒ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → Place Customer Number Bar Code Label here

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☒ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Michael I. Wolfson	24,750	Mark Montague	36,612
William H. Dippert	26,723		
R. Lewis Gable	22,479		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Eilaz	Babaev

Inventor's Signature	[signature]					Date	9-25-00
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Post Office Address							
City	Minnetonka	State	MN	ZIP	55343	Country	US

☐ Additional inventors are being named on the ____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto